FAXBACK 12946 9441.1987(45)

CONTAINERS USED TO HOLD LISTED CHEMOTHERAPY DRUGS

JUN 16 1987

Mr. Fred Kamienny Vice President PRN Service, Inc. 1210 Morse Royal Oak, Michigan 48067

Dear Mr Kamienny:

This responds to your letter of April 13, 1987, regarding the regulatory status of chemotherapy drugs and related supplies. In particular, you questioned whether the weight of the "empty" vial should be included in determining the amount of drug residues to be disposed.

As you pointed out, several chemotherapy drugs are listed in 40 CFR 261.33(f) (commonly known as the U-list). As such, these wastes are regulated under the EPA hazardous wastes regulations (unless subject to the small quantity generator exclusion). Included in the listing are the following discarded commercial chemical products, off-specification species, container residues, and spill residues:

- 1) chlorambucil (U035)
- 2) cyclophosphamide (U058)
- 3) daunomycin (U059)
- 4) melphalan (U150)
- 5) mitomycin C (U010)
- 6) streptozotocin (U206)
- 7) uracil mustard (U237)

Under EPA regulations governing the management of hazardous wastes, any container used to hold these chemicals (such as vials) are considered hazardous wastes unless these containers meet the criteria of an "empty container." Under the empty container provisions such vials are excluded from regulation if the material has been removed by pouring, pumping, and aspirating, and no more than 1 inch of residue remains in the bottom of the vial or no more than 3 percent by weight of the total capacity of the container remains in the container. (See 40 CFR 261.7)

The Agency is aware, however, that prudent practice dictates

that materials contaminated with these chemicals (such as syringes, vials, gloves, gowns, aprons, etc.) not be handled after use. Therefore, to minimize exposure to these toxic chemicals, the

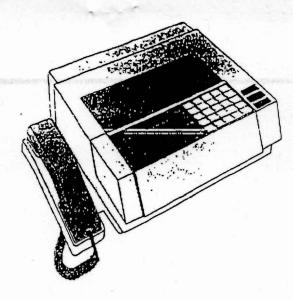
Agency recommends that the entire volume of waste be weighed and that there be no attempt to remove any residue from the vial before disposal.

Chemotherapy drugs that are not listed hazardous wastes are not regulated by EPA. However you should contact your State or local government regarding the management of these chemicals. Also, the National Institutes of Health (NIH) provides guidance on handling and management of antineoplastics. Contact Harvey Rogers, at NIH for further information. Mr. Rogers may be reached at (301) 496-7775.

If you should have any further questions regarding regulatory requirements for specific wastes, you may call RCRA Hotline at (800) 424-9346, or contact Mitch Kidwell, of my staff, at (202) 382-4805.

Sincerely,

Jacqueline W. Sales, Chief Regulation Development Section



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FACILITIES & CONSTRUCTION DEPT.

T0 :	Mariansa Pomerquey EPA	
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FROM:	JAMES B. 17064E TI	
SUBJECT:		
MESSAGE:	Non-trade and a second of the contract of the	
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		t of April
# OF DACES	S SENDING INCLIMING COVER SHEET.	

ORUG	Purchased	USED 2003	On Hand	Purchased
	2003 in mg		2/9/04	2004 in mg
Bleomycin	60 <u>units</u>	60 <u>units</u>	60 units	0
Blenoxane)	(not in mg)	(not in mg)	(not in mg)	1400
Carboplatin	27450	24135	150	1400
Paraplatin)		440.5	250	150
Cisplatin	7000	6635	350	150
(Platinol)				0
Cladribine	70	59.5	-	U
(Leustatin)			2500	(000
Cyclophosphamide	174000	137681	7500	6000
(Cytoxan)			5100	1000
Cytarabine	15200	6100	5100	1000
(Cytosar)				
Dactinomycin	4	4 borrowed by	4	0
(Cosmegen)		another hosp 9/03		
Dacarbazine	800	0	900	0
(DTIC)				1500
Docetaxel	14560	12619	380	1200
(Taxotere)				
Doxorubicin	11190	10143.3	540	700
(Adriamycin)				
Etoposide	2600	3890	700	1100
(Vepesid)				
Fluorouracil	417000	417323	70000	20000
(5FU, Adrucil)				
Gemcitabine	63200	63275	2800	4800
(Gemzar)			-	
Goserelin	194.4	158.4	7.2	2
(Zoladex)	1			
Idarubicin	360	206	120	100
(Idamycin)				
Ifosfamide	14000	0	0	0
(Ifex)				
Irinotrecan	4240	4504	240	140
(Camptosar)	1,2,10	1,5 %		
Leuprolide	135	172.5	11.25	2205
(Lupron)	133			
Methotrexate	4700	2799	750	700
Mitomycin	220	96	110	5
	220	100		
(Mutamycin)	10800	7895.3	1500	1700
Paclitaxel	10800	7075.3		
(Taxol)	5500	3475	800	3200
Rituximab	5500	34/3	000	1
(Rituxan)	20100	26705	1320	0
Trastuzumab	29480	26785	1320	
(Herceptin)	J	0150	9	2
Vincristine	119	215.8	9	2
(Oncovin)		- 620	130	0
Vinorelbine	620	610	130	,

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